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October 20, 1999

Docket No. 99N-3089
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Draft Affirmative Agenda for CFSAN's International Activities

(Docket No. 99N-3089)

Dear Sir or Madam:

The Food Marketing Institute (FMI) is pleased to respond to the Food and Drug Administration's (FDA's) request for comments on the "Draft Affirmative Agenda for International Activities." 64 Fed. Reg. 50518 (Sept. 17, 1999). As discussed more fully below, FMI fully supports the international agenda's emphasis on monitoring, inspection, and traceback activities for foods produced abroad, as well as the goal of developing systems to evaluate international food regulatory and food production systems.

FMI is a non-profit association that conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 members and their subsidiaries. Our membership includes food retailers and wholesalers, as well as their customers, in the United States and around the world. FMI's domestic member companies operate approximately 21,000 retail food stores with a combined annual sales volume of \$220 billion, which accounts for more than half of all grocery sales in the United States. FMI's retail membership is composed of large multi-store chains, small regional firms, and independent supermarkets. Our international membership includes 200 members from 60 countries.

FDA's "Draft Affirmative Agenda for International Activities" sets forth FDA's priorities for international food safety activities for the next three years. Of the areas identified, we believe the following are the most important. Our recommendations are consistent with comments filed with the Agency on September 30, 1999 regarding the Center for Food Safety and Applied Nutrition's (CFSAN's) overall program priorities for the year 2000.

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First, we agree that FDA should increase surveillance of imported foods, especially fresh produce, at U.S. borders, and otherwise enhance programs to ensure that imported foods meet U.S. food safety requirements. Toward this end, FDA should coordinate with the U.S. Department of Agriculture to redirect the inspection resources freed up as a result of the implementation of the Hazard Analysis Critical Control Point program in meat processing facilities toward a stronger border surveillance program for imported produce.

Establishing criteria for evaluating international food regulatory systems and conducting evaluations in accordance with those criteria will be important components of this effort. Developing protocols for and conducting assessments of the food production infrastructure and food safety systems of those foreign countries that are major suppliers of fresh fruits and vegetables to the United States will be similarly instrumental. We recommend that FDA conduct these assessments to ensure the safety of the food that is imported into the United States, as well as for the stated goals of identifying educational and technical assistance needs.

Second, we agree that FDA should conduct traceback investigations when and where appropriate to determine the cause of foodborne illness outbreaks that occur in the United States as a result of imported foods. Of course, appropriate follow up steps should be implemented to minimize the likelihood for future outbreaks to occur as a result of the same causes.

Third, we agree that FDA should participate in the recently convened Ad Hoc Intergovernmental Codex Task Force on Foods Derived from Biotechnology for the stated purpose of "developing consensus international guidance for assessing the safety of foods obtained from biotechnology." Sound international standards for foods produced from biotechnology will be essential to harmonious trade relationships. FDA, which is an internationally recognized and respected scientific regulatory body, is uniquely situated to ensure that the standards developed by Codex are based on sound science. FDA should recommend and support a science-based policy consistent with the Agency's May 1992 policy statement that addresses foods derived from modern biotechnology. See 57 Fed. Reg. 22984 (May 29, 1999).

We appreciate the opportunity to provide our comments on FDA's draft Affirmative Agenda for International Activities. If we may be of assistance in any way, please do not hesitate to call on us.

Cordially yours,

Tim Hammonds
President and CEO



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